

3.4 ORGAN PROCUREMENT, DISTRIBUTION AND ALTERNATIVE SYSTEMS FOR ORGAN DISTRIBUTION OR ALLOCATION. The following policies apply to organ procurement, distribution and alternative systems for organ distribution or allocation.

- 3.4.1 Time Limit For Acceptance.** A transplant center, or its designee, must access donor information within UNetSM within one hour of receiving the initial organ offer notification. If UNetSM is not accessed within one hour by the transplant center or its designee, the offer will be considered refused. Once the appropriate donor information is provided as described in Policies 3.5.9, 3.6.9, 3.7.12, and 3.8.5, a transplant center shall be allowed one hour from the time of accessing the donor information, except as otherwise provided in Policies 3.5.3.5 (Time Limit) and 3.8.1.6.1 (Time Limit), in which to communicate its acceptance or refusal of the organ. After one hour elapses, or shorter period as defined under Policies 3.3.5 and 3.8.1.6.1, without a response, the offer will be considered refused and the offering entity may offer the organ to the transplant center(s) for the patient(s) listed next in priority on the match list.
- 3.4.2 Multiple Organ Retrieval.** After a Member indicates its initial acceptance of an organ, the transplant centers or OPOs involved must agree upon the time that multiple organ procurement will begin. If the procurement time cannot be agreed upon, the Host OPO may withdraw the offer from the transplant center or OPO unable to agree upon a time for procurement to begin.
- 3.4.3 Department of Defense Directive.** Until such time as the OPTN and the Department of Defense (DOD) reach a mutual understanding on organ allocation policies, Members may cooperate with U.S. military facilities that are bound by DOD organ allocation directives which are in conflict with policies. However, the OPTN neither agrees with nor endorses present DOD directives.
- 3.4.4 Multiple Organs Offer.** If an OPO has permission to procure all organs from a particular donor, that OPO shall offer those organs through the Match System unless there is a contraindication to organ procurement.
- 3.4.5 National Distribution of Organs.** After an organ has been unsuccessfully offered to appropriate Members for allocation to local candidates or unsuccessfully offered to Members through an approved regional sharing arrangement, the Organ Center will allocate an abdominal organ first regionally, and then nationally, based upon the point system set forth in policies. The Organ Center will allocate thoracic organs according to Policy 3.7.
- 3.4.6 Receiving and Responding to Organ Offers.** Transplant centers must accept organ offer notifications in an electronic manner compatible with at least one of the options provided by UNetSM. Additionally, transplant centers must view organ offers and respond to these offers in an electronic data format (e.g., via Internet access) through UNetSM.
- 3.4.7 Application, Review, Dissolution and Modification Processes for Alternative Organ Distribution or Allocation Systems.** The following policies define the processes for applying for a new or modified AAD System, review of such systems and withdrawal from such systems by any one or more of the participants.
- 3.4.7.1 Application.** Applications to allocate organs locally using alternative point assignment systems may be submitted by OPOs, Members participating in a Board approved ALU or Members participating in a Board approved sharing arrangement. In each case, the application must indicate for each OPO and transplant center that is to take part in the alternative point assignment system whether or not the institution supports the system. Applications to distribute organs according to sharing arrangements or ALUs may be submitted by OPOs; any such application must indicate for each applicant OPO whether or not the OPO's Board of Directors supports the sharing arrangement or ALU, as applicable. In cases where unanimity cannot be achieved at the local level,

applications to allocate organs using either an alternative point assignment system, sharing agreement or ALU must have approval of 75% of the Member OPOs and or transplant centers.

Applications to allocate organs using alternative point assignment systems or to distribute organs using sharing arrangements or ALUs are submitted to the appropriate organ-specific committees for consideration before being issued for public comment according to processes for public comment. Such applications are then reconsidered by the relevant Committee in light of public comment. Final applications to allocate organs locally using alternative point assignments or to distribute organs using sharing arrangements or ALUs must be presented to and approved by the Board of Directors before they can be implemented or used in organ allocation/distribution. An application to allocate organs locally using an AAD System must specify the purpose for which it is proposed, how the system is intended to accomplish this purpose, and an evaluation plan by which the participating Members will assess the system's success in achieving its stated purpose. The evaluation plan must include objective criteria for measuring the AAD System's results, including, for example, (a) candidate waiting time (stratified by candidate populations), (b) graft survival (stratified by recipient populations), and (c) organ availability and/or organ quality. Applicants are encouraged to explain in the evaluation plan any difficulties they anticipate in demonstrating results from the AAD system that would assist the reviewing committees in assessing the system. This might include, for example, low volumes and difficulties in establishing statistical significance even over relatively long periods of time in the case of a system intended to adjust priority for pediatric candidates. The relevant reviewing committees and/or Board of Directors may specify criteria in addition to those proposed by the Members for the Members to address in assessing the ongoing operations of the AAD System.

Applications shall comply with other application requirements as may be established by the appropriate committees and Board of Directors. Once approved, notice of the AAD System will be included in the policies. Initial approval by the Board of Directors of any AAD System shall be on a provisional basis for a period of 3 years. By the end of this period, the applicable Members must have demonstrated through objective criteria that the purpose for which the system was approved has been achieved or at least that progress considered adequate and demonstrated to the satisfaction of the reviewing committee(s)/Board to this end has been accomplished. At the end of the provisional approval period, the appropriate reviewing committees will recommend to the Board of Directors that the AAD System be: (a) finally approved, (b) approved on a continued provisional basis for a specific period of time, or (c) terminated.

When an alternative point assignment system, sharing arrangement or ALU is proposed to permit participation of a distribution unit in a scientific study to test a stated hypothesis with defined parameters under controlled conditions, such an alternative point assignment system, sharing arrangement or ALU may be approved by the Board of Directors for implementation if it (a) is of scientific merit (The Board may consider prior approval of such national agencies as the National Institutes of Health, Veterans Administration or national voluntary health agencies in making this determination); (b) extends for a defined, limited time period not greater than the initial 3-year provisional period, plus 2 years; and, (c) will have no net effect on the number of organs available for transplant within the applicable distribution unit, or potentially affected larger distribution units which include the applicable distribution unit. Such proposals will be considered in accordance with the standard process for consideration of alternative point assignment systems, sharing arrangements or ALUs, as applicable.

3.4.7.2 Data Submission Requirements. Members receiving permission of the Board of Directors for evaluating alternative point assignment—systems, sharing arrangements and ALUs, including those denied with conditions and those approved on a provisional basis, shall submit, at one-year intervals, or more frequently upon request, relevant data and status reports that assess the impact of the AAD System, relative to the system's stated objectives and using the performance measures proposed in the participating Members' application, address any organ allocation problems that may have arisen as a result of the system and, in the case of ALUs, demonstrate adherence to the principles for defining local (Policy 3.1.9) and progress toward correcting or at least reducing the inequity that the ALU is intended to address. From time to time, these Members may be provided with data reports (from UNetSM) showing the experience of the alternative organ distribution\allocation system as well as the national system for various risk factors. Any such reports will be available for use by the Members, along with any other information the Members would like to provide, in assessing and/or explaining the impacts of the system. Members receiving approval by the Board of Directors to participate in an alternative point assignment system, sharing arrangement or ALU as part of a limited duration scientific study shall be subject to the data submission requirements stipulated above in addition to submission of a final report within six months following completion of the study.

The appropriate committee(s) shall actively monitor these data and status reports to provide consistency to efforts to assist the participating OPOs and transplant centers in dealing with each of their special circumstances; to make recommendations to the Board of Directors for continuation, modification or termination of the AAD Systems; and, in the case of alternative point assignment systems to review the alternative system in light of standard organ allocation policies. This provision shall not be interpreted to limit or otherwise affect the Board of Directors' authority to revoke or suspend operation of any AAD System as deemed appropriate by the Board of Directors.

3.4.7.3 Dissolution of Alternative Assignment Systems Sharing Arrangements and ALUs. Members operating with an approved (a) alternative point assignment system who unanimously elect to withdraw from that system and use the standard point system criteria pursuant to Policies 3.5 through 3.11, (b) sharing arrangement who unanimously elect to withdraw from that arrangement and define the OPOs as the Local Units for purposes of organ distribution or (c) ALU who unanimously elect to withdraw from that ALU and use the OPO, or larger sharing area under a Board approved sharing arrangement, as the Local Unit pursuant to Policy 3.1.7, shall provide timely written notification of such withdrawal and resulting dissolution of the alternative point assignment system, sharing arrangement or ALU, as applicable, to the relevant Region, appropriate committees and the Board of Directors. Dissolution of the alternative point assignment system, sharing arrangement or ALU, as applicable, shall be effective after appropriate re-programming on UNetSM. A request to withdraw from an alternative point assignment system, sharing arrangement or ALU that is not unanimous among the parties who obtained approval of the system shall be considered a proposal to modify the system in accordance with the process described in Policy 3.4.6.4 below.

3.4.7.4 Modifications of Alternative Point Assignment Systems, Sharing Arrangements and ALUs. Any proposed modification of an approved alternative point assignment system, sharing arrangement or ALU, other than a proposal to dissolve the system agreed to unanimously by the parties, shall require application by the participating Member(s) in the case of an alternative point assignment system, or participating OPOs in the case of a sharing arrangement or ALU, and approval by the Board in accordance with the application process described in Policy 3.4.6.1 above.

3.4.7.5 AAD Systems Approved Prior to March 15, 2005. Members using an approved AAD System as of March 15, 2005, that meets the criteria for such system in effect prior to that date, shall be permitted to continue the system for 3 years from March 2005, at which time they will be required to re-apply to continue their systems under the requirements and criteria of applicable policies for AAD Systems then in effect

3.4.8 Application, Review, Dissolution and Modification Processes for Variances. The following policies define the processes for applying for a new or modified Variance, review of such systems by, and withdrawal from such systems by any one or more participants.

3.4.8.1 Application. Applications to allocate or distribute organs using a Variance may be submitted by OPOs, Members participating in a Board approved ALU or Members participating in a Board approved Sharing Arrangement. In each case, the application must indicate for each OPO and transplant center that is to take part in the Variance whether or not the institution supports the system. Unanimity among participants is encouraged but not required. In cases where unanimity cannot be achieved, Variance applications must include statements of support or opposition on behalf of each potential participant explaining their position. Variance applications are submitted to the appropriate organ-specific committees for consideration before being issued for public comment according to processes for public comment. Variance applications are then reconsidered by the relevant Committee in light of public comment. Final Variance applications must be presented to and approved by the Board of Directors before they can be implemented on UNetSM or used in organ allocation/distribution. Once approved, notice of the Variance will be included in the policies.

A Variance must comply with application requirements as may be established by the appropriate committees and Board of Directors and specify the purpose for which it is proposed, incorporating a review of the method for improving organ allocation or distribution; how the system is intended to accomplish this purpose; and a plan for data collection and analysis for assessment of the system's success in achieving its stated purpose. The relevant reviewing committees and/or Board of Directors may specify criteria in addition to those proposed by the Members for the Members to address in assessing the ongoing operations of the policy variance. The plan must include a defined end-point by which the Variance will be completed and results reported.

Once a Variance is approved, Members participating in the variance are required to fulfill all stipulations agreed to in their application and comply with the data submission and other requirements included in Policy 3.4.7.2. Participants in an approved Variance are further required to stay aware of all applicable provisions of the organ allocation policies and any amendments thereto as well as other bylaws and policies.

3.4.8.2 Data Requirements. Members receiving permission of the Board of Directors for evaluating Variances shall submit, at one-year intervals, or more frequently upon request, relevant data and status reports that: (i) assess the impact of the Variance relative to the system's proposed effect and in accordance with the plan for data collection and analysis defined in the participating Members' application, and (ii) address any organ allocation problems that may have arisen as a result of the system. From time to time, these Members may be provided with data reports (from UNetSM) showing the experience of the variance as well as the national system for various risk factors. Any such reports will be available for use by the Members, along with any other information the Members would like to provide, in assessing and/or explaining the impacts of the system. In addition to the periodic reports stipulated above, Variance participants must submit a final report within six months following completion

of the plan.

The appropriate committee(s) shall actively monitor these data and status reports to review the Variance and any potential for improving standard national organ allocation policies. This provision shall not be interpreted to limit or otherwise affect the Board of Directors' authority to revoke or suspend operation of any Variance as deemed appropriate by the Board of Directors.

3.4.8.3 Appeal to Secretary. Decisions of the Board of Directors to approve a Variance may be appealed to the Secretary of HHS in accordance with the OPTN Final Rule, 42 CFR § 121.4.

3.4.8.4 Termination of Member Participation in Variance. Members operating with an approved Variance who unanimously elect to withdraw from the variance and use the standard allocation and distribution system criteria pursuant to applicable policies shall provide timely written notification of such withdrawal and resulting termination of Variance to the relevant Region(s), appropriate committees and the Board of Directors. Termination of the Variance shall be effective after appropriate re-programming on UNetSM. A request to withdraw from a Variance that is not unanimous among the parties who obtained approval of the system shall be considered a proposal to modify the system in accordance with the process described in Policy 3.4.7.5 below.

3.4.8.5 Modification of Variance. Any proposed modification of an approved Variance, other than a proposal to dissolve the variance agreed to unanimously by the parties, shall require application by the participating Member(s), and approval by Board of Directors in accordance with the application process described in Policy 3.4.7.1 above.

3.4.9 Development, Application, Review, Dissolution and Modification Processes for Committee-Sponsored Alternative Systems. The following policies define the processes for developing a new or modified Committee-Sponsored Alternative System, application to participate in such systems, review of such systems, and withdrawal from such systems by any one or more participants.

3.4.9.1 Development and Application. Committee-Sponsored Alternative Systems are developed by the applicable reviewing Committee(s), submitted for public comment according to processes for public comment, and reconsidered by the sponsoring Committee in light of public comment. Final proposals for Committee-Sponsored Alternative Systems must be presented to and approved by the Board of Directors prior to implementation on UNetSM. Once approved, notice of the Committee-Sponsored Alternative System will be included in the policies. A Committee-Sponsored Alternative System must specify the purpose for which it is proposed, how the system is intended to accomplish this purpose, and an evaluation plan by which the sponsoring Committee will assess the system's success in achieving its stated purpose. The evaluation plan must include objective criteria for measuring the Committee-Sponsored Alternative System's results, including, for example, (a) candidate waiting time (stratified by candidate populations), (b) graft survival (stratified by candidate populations), and (c) organ availability and/or organ quality. Committees are encouraged to explain in the evaluation plan any difficulties they anticipate in demonstrating results from the Committee-Sponsored Alternative System that would assist the reviewing committees in assessing the system. This might include, for example, low volumes and difficulties in establishing statistical significance even over relatively long periods of time in the case of a system intended to adjust priority for pediatric candidates. The system must be established for a defined period of time, during which the sponsoring Committee must collect and evaluate relevant data to assess whether the system is achieving its objectives and should be continued, modified, or terminated. By the end of this period, the sponsoring Committee must have demonstrated

through objective criteria that the purpose for which the system was approved has been accomplished or at least that progress considered adequate and demonstrated to the satisfaction of the reviewing committee(s)/Board to this end has been attained. Based upon this assessment, the sponsoring Committee shall recommend to the Board of Directors whether the Committee-Sponsored Alternative System should be continued without change, modified, or terminated.

OPOs and their affiliated transplant centers may apply to participate in an approved Committee-Sponsored Alternative System by demonstrating unanimous agreement to such participation among the OPO(s) and their transplant centers with programs for transplantation of the applicable organ(s). For those OPOs with multiple units (ALUs), signatures must be obtained from each transplant center within the OPO (with programs for transplantation of the applicable organ(s)) indicating that they agree to participate in the system. Applicants also must provide Member contact and other information as may be determined by the appropriate Committees and Board of Directors. Once the Board of Directors has approved a Committee-Sponsored Alternative System, individual participant applications do not require Committee or Region review or Board approval prior to implementation on UNetSM. Participants in Committee-Sponsored Alternative Systems are required to stay aware of all applicable provisions of the organ allocation policies and any amendments thereto as well as other bylaws and policies.

3.4.9.2 Data Requirements. Members participating in a Board-approved Committee-Sponsored Alternative System are not required to submit alternative system data other than any specific data submission requirements of the system.

3.4.9.3 Termination of Member Participation in Committee-Sponsored Alternative System. An OPO and its affiliated transplant centers participating in an approved Committee-Sponsored Alternative System may unanimously elect to withdraw from the alternative system and use the standard allocation and distribution system criteria pursuant to applicable policies upon providing timely written notification of such withdrawal and resulting termination of participation in the alternative system to the relevant Region(s), appropriate committees and the Board of Directors. Termination of the Members' participation in the alternative system shall be effective after appropriate re-programming in UNetSM.

3.4.9.4 Modification of Committee-Sponsored Alternative System. Any proposed modification of an approved Committee-Sponsored Alternative System, other than withdrawal by individual participant(s), shall require application by the sponsoring Committee, and approval by Board of Directors in accordance with the application process described in Policy 3.4.8.1 above.

3.4.9.5 Committee-Sponsored Alternative Systems Approved Prior to March 15, 2005. Committee-Sponsored Alternative Systems approved by the Board of Directors as of March 15, 2005, shall be permitted to continue to operate for 3 years from March 2005, at which time the applicable sponsoring Committees will be required to re-apply to continue the systems under the requirements and criteria of applicable policies for Committee-Sponsored Alternative Systems then in effect.

3.4.10 Allocation of Organs During Regional/National Emergency Situations. In the event of a regional or national emergency situation that compromises telecommunications, transportation, or the function of / access to the waiting list and UNetSM, a notice and instructions will be distributed, if possible, to all transplant centers and organ procurement organizations advising them of the impact of the situation on the system and how members should proceed with organ allocation, distribution and transplantation. Members should reference Policies 3.4.7.1; 3.4.7.2; and 3.4.7.3 in cases of

regional/national emergency.

3.4.10.1 Regional/National Transportation Disruption. In these situations, the OPTN contractor and members are able to communicate and the waitlist and matching systems are accessible, but transportation of organs is either not possible or severely impaired. Members are required to contact the OPTN contractor to determine proper operating procedures.

3.4.10.2 Regional/National Communications Disruption. In these situations, the OPTN contractor and members are unable to communicate through one or more of the available communications methods (internet and phones) and the waitlist and matching system are operational.

Internet Outage. Members are required to contact the OPTN contractor and determine the proper operating procedures.

Telecommunications (Land and Mobile Phone) Outage. Internet contact with the OPTN contractor should be made via e-mail to determine operation procedures and to obtain assistance. Members will continue to use the waitlist and matching system for organ allocation and distribution. Organ procurement organizations must document any variations in allocation or distribution due to telecommunications problems for submission to the OPTN contractor.

Combined Outage. In these situations, the OPTN and members are unable to communicate through any communications method and the waitlist and matching system are not accessible. The organ procurement organizations should reference recent matched of similar ABO and body size for ranking local transplant candidates. If a similar match is available, the local organ procurement organization should use local transplant program waiting lists to best match the donor organ with waiting transplant candidates. Organ procurement organizations must document their process for allocation for submission to the OPTN contractor.

3.4.10.3 Operational Disruption. In these situations, the OPTN contractor and members are unable to communicate through any communications method and the waitlist and matching system are not operational. The organ procurement organizations should reference recent matched of similar ABO and body size for ranking local transplant candidates. If a similar match is available, the local organ procurement organization should use local transplant program waiting lists to best match the donor organ with waiting transplant candidates. Organ procurement organizations must document their process for allocation for submission to the OPTN contractor.